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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/765,695	07/25/97	ABRAHMSEN	L A96335US
EXAMINER			

026271 HM12/0417
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ART UNIT	PAPER NUMBER
SCHWABRON, R	30

1644

DATE MAILED: 04/17/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 11/18/99, 4/10/2000 and 8/4/2000

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 36-38, 44-47, 52-57 is/are pending in the application.
Of the above, claim(s) 53-57 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 36-38, 44-47, 52 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☒ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. Regarding the various petitions filed under 37 CFR 1.181, as per the Petition decision mailed 3/26/2001, said petitions have been denied.
2. Applicant's election of the species SEA in Paper No. 25 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 53-57 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected species. Election was made **without** traverse in Paper No. 25.
4. Claims 36-38,44-47,52 are under consideration. Claim 52 is newly added. Claims 14-35,39-43,48-51 have been cancelled.

RESPONSE TO APPLICANTS ARGUMENTS

5. The amendment filed 11/18/99 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows.

The new abstract in the amendment filed 11/18/99 does not recite that the two components of the conjugate are covalently linked. There is no support in the specification as originally filed for a conjugate wherein the two components are linked by other than a covalent linkage.

Applicant is required to cancel the new matter in the reply to this Office action.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 36-38,44-47,52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dohlsten et al. (1991).

Dohlsten et al. teach SEA/ antibody conjugates wherein the SEA portion of the conjugate portion binds T cells and the antibody portion of the conjugate binds a tumor antigen (see Abstract). Dohlsten et al. teach that said conjugate can activate T cells to lyse tumor cells that express the antigen bound by the antibody portion of the SEA/antibody conjugate (see abstract). Dohlsten et al. teach that SEA binds VB of the TCR of T cells. Dohlsten et al. teach that said conjugates can be used to treat disease (see Abstract, last sentence) including cancer (see page 9291, second column). SEA is a superantigen requiring zinc ions for binding to MHC class II (eg. see claim 50). The SEA and antibody are "fused together". SEA is as staphylococcal enterotoxin (see Abstract). An antibody is a "polypeptide structure" and a "biospecific affinity counterpart" (see claim 45). Dohlsten et al. do not teach that the superantigen portion of the conjugate has been mutated to show a modified ability to bind to MHC class II. Regarding the SEA/antibody disclosed in said publication, Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules" (see page 9291, column 1). Dohlsten et al. teach that MHC class II binding in SEA and other superantigens has been localized to the C-terminal region (see page 9291, first column). Dohlsten et al. teach that using such information, SEA/antibody conjugates with reduced MHC class II binding could be prepared (see column 1, page 9291). A routineer would have prepared such conjugates using routine experimentation. Dohlsten et al. teach that it would have been desirable to produce such mutated conjugates to decrease binding of the conjugate to nontumor cells which express MHC class II (see column 1, page 9291). The zinc binding region of the superantigen is found in the C-terminus. It would have been prima facie

obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Dohlsten et al. teach SEA/ antibody conjugates wherein the SEA portion of the conjugate portion binds T cells and the antibody portion of the conjugate binds a tumor antigen and the use of said conjugates to kill tumor cells, and Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules". One of ordinary skill in the art would have been motivated to prepare such conjugates because Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules".

Regarding applicants comments, applicant refers to the "G.H., unpublished data" citation in page 9291 of the Dohlsten et al. reference and summarizes data related to said citation (data that was not present in the Dohlsten et al. publication). In view of the fact that applicants representative is not an author of said publication, his comments regarding the unpublished (and undisclosed) data are not considered. It is suggested that comments related to said "G.H., unpublished data" be submitted by an actual author of said publication, in the form of a declaration. Furthermore, assuming arguendo that said comments were considered, the claims under consideration do not recite that the mutation occurs in the c-terminus region (eg. they merely recite the superantigen has a mutated ability to bind MHC class II). Furthermore, depending on how the term c-terminus is interpreted, even the construct disclosed in page 8 of the instant amendment would localize the MHC class II binding to the c-terminal portion of the molecule. Regarding applicants comments about a Kim et al. and a Jardetzky et al. reference, said references were not of record in the instant application, and copies of said references were not provided, so said references and comments related to said references were not considered. Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules" (see page 9291, column 1). Dohlsten et al. teach that MHC class II binding in SEA and other superantigens has been localized to the C-terminal region (see page 9291, first column). Dohlsten et al. teach that using such information, SEA/antibody conjugates with reduced MHC class II binding could be prepared (see column 1, page 9291). A routineer would have prepared such conjugates using routine experimentation. Dohlsten et al. teach that it would have been desirable to produce such mutated conjugates to decrease binding of the conjugate to nontumor cells which

express MHC class II (see column 1, page 9291).

8. No claims is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 08/765695
Art Unit 1644

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RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

A handwritten signature in black ink, appearing to read 'R B Schwadron', written in a cursive style.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644